

IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE

Applicant(s): Malakowski, et. al. )  
)  
Serial No.: 09/764,609 )  
)  
Filed: January 17, 2001 )  
)  
For: Surgery System )  
)  
Group Art Unit: 3739 )  
)  
Examiner: Leubecker )  
)  
Docket No.: 29997/035A )  
)  
Customer No.: 29471 )

RECEIVED  
APR 16 2004  
TECHNOLOGY CENTER R3700

**Declaration of Dr. Jay H. Klarsfeld, M.D. made under Rule 132**

I, Jay H. Klarsfeld declare as follows:

1. That I am a surgeon specializing in Otolaryngology (ear, nose, and throat) and my Curriculum Vitae outlining my education and specializations is attached as Exhibit A.
2. That I am currently a consulting surgeon for the Stryker Corporation, a related entity to the assignee of the present application.
3. That I am familiar with the use of surgical navigation systems and instruments in the ear, nose and throat area and in particular in sinus surgery and I have used a number of different surgical navigation systems in the past including passive navigation tracking systems and a system that uses wireless hand pieces of the type as claimed in the present application. As noted in my Curriculum Vitae, I have lectured on the use of image guided technology (surgical navigation) for sinus and other surgeries.
4. That I understand that the present patent application is claiming the use of wireless communication between the surgical navigation system and the individual instruments in combination with other elements of the currently pending claims

5. That I understand that the current application has been rejected because the invention as claimed is considered obvious in view of a patent that discloses a wired or tethered instrument communicating with a surgical navigation system.

6. That I believe that the use of wireless communication between an active smart instrument and a surgical navigation system has been recognized as a significant advance today and I believe it would not have been considered as obvious on January 27, 2000 for the reasons set forth below:

a. The use of a wireless system simplifies the setup prior to a typical ear nose and throat surgery such as a sinus surgery, and after using a wireless system, I would not use a hard wired optical system;

b. In sinus surgery there are a large number of instruments and devices in the surgical field that require power cords, suction tubes and the like. A listing of the typical instruments that are often simultaneously present in the surgical field for sinus surgery is attached as Exhibit B. A typical hardwired system will add from 3 to 5 wires to the surgical field.

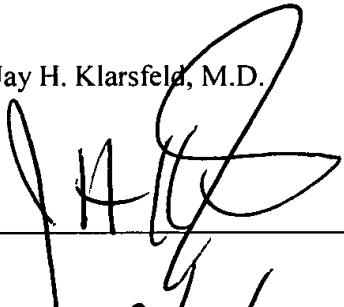
c. The use of a wireless hand piece that can be tracked by the surgical navigation system is much less cumbersome and provides a significantly greater range of motion to me in performing these surgical techniques allowing me to perform these tasks properly, in less time, and with lower fatigue. A wired hand piece has a wire that drags, can catch on other instruments and wires, and will actually pull against the direction I need to move the hand piece. In addition, for optical systems, it is important to be able to face the tracking device towards the camera at all times. The inclusion of wires make it more difficult to properly angle the tracking device so the device is visible to the cameras.

d. The use of a wireless hand piece minimizes issues relating to maintenance of the surgical field in a sterile state because there is no requirement to pass a portion of the cord to a technician to attach the hand piece to the surgical navigation computer.

e. In my view the wireless, hardwired issue is so important that a number of companies that make tracking implements and devices have abandoned hard-wired active optical systems in favor of passive wireless optical systems and have not developed wireless active optical tracking devices as claimed in the present application.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the above referenced application or any patent issued thereon.

Jay H. Klarsfeld, M.D.



Date: 3/30/04

Exhibit A  
Curriculum Vitae

Jay H. Klarsfeld, M.D.

HOME ADDRESS

38 Farview Farm Road  
West Redding, CT 06896  
(203) 938-2287  
E-Mail ENT40@aol.com

OFFICE ADDRESS

107 Newtown Road, Suite 2A  
Danbury, CT 06810  
Telephone: (203) 830-4700  
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BOARD CERTIFICATION

Fellow of the American Academy of Otolaryngology  
Head and Neck Surgery – 1986

EDUCATION

1977 Brandeis University – Double Major – Biochemistry and Biology  
1981 Mount Sinai School of Medicine – M.D.

POST GRADUATE TRAINING

1979 - Anesthesia Preceptor Program. The Mount Sinai Medical Center,  
New York  
1981 – 1982 Internship General Surgery. The Mount Sinai Medical Center,  
New York  
1982 – 1983 Resident General Surgery. The Mount Sinai Medical Center,  
New York  
1983 – 1985 Resident, Department of Otolaryngology. The Mount Sinai Medical  
Center, New York  
1985 – 1986 Chief Resident, Department of Otolaryngology. The Mount Sinai  
Medical Center, New York

EMPLOYMENT

1994 – Present President, Advanced Specialty Care, P.C. – Multi-Specialty Surgical Group  
1990 – 1994 Partner– Advanced Ear, Nose & Throat Care, P.C.  
1986 – 1990 Employee Physician & Surgeon – Gary Townsend, MD, P.C.

HOSPITAL POSITIONS

2003 – Present Chairman Surgical Services Committee – Danbury Hospital  
1992 – 1995 Medical Advisory Board Danbury Surgical Center  
1991 – 1993 Secretary / Treasurer, Department of Surgery – Danbury Hospital

AFFILIATIONS

Danbury Hospital  
Danbury Healthsouth Surgical Center  
New Milford Hospital

TEACHING APPOINTMENTS

Attending Surgeon, Section Otolaryngology; Head& Neck Surgery; Danbury Hospital  
Work with Surgical Resident who have specific interest in Head & Neck Sugery  
Clinical Instructor – Otolaryngology Mount Sinai Service, Elmhurst Queens till 1997  
Clinical Instructor – Otolaryngology University Medical Center, Yale New Haven,  
New Haven, CT till 2002

AWARDS

1977 Cum Laude – Brandeis University  
1981 Lester R. Tuchman Award for Clinical Excellence.  
Mount Sinai School of Medicine

MEDICAL LICENSE

State of New York - #152750  
State of Connecticut - #027179

#### MEDICAL CONSULTING EMPLOYMENT

2001 – 2002      BrainLAB Corporation  
2003 – Present    Stryker Leibinger Corporation  
2004 – Present    Editorial Board of “Outpatient Surgery Magazine”

#### PROFESSIONAL SOCIATES

Alpha Omega Alpha Medical Honor Society  
American Academy of Otolaryngology – Head and Neck Surgery – Fellow  
American Academy Ambulatory Surgery Centers  
American Rhinologic Society  
Connecticut State Medical Society  
Danbury Medical Society  
Fairfield County Medical Society  
New York Metropolitan Facial Plastic Surgery Society – Charter Member

#### PUBLICATIONS

1. Klarsfeld, J., : Surgical Therapeutic Approach to the Management of Full Thickness Burns. Mt. Sinai J. Med. 48 (5): Sept – Oct., 1981
2. Klarsfeld, J., Edelstein, D. and Biller, H.F.: Benign and Malignant Schwannomas of the Brachial Plexus. (Accepted to the American Academy of Otolaryngology – Head and Neck Surgery), Fall Meeting, October 1985
3. Klarsfeld, J., Sacks, S.H., and Green, R.P.: Radical Neck Dissections Necessitated by a Retro Pharyngeal Abscess. New York State Journal of Medicine, Vol. 87, October 1987, 567 – 569
4. Klarsfeld, J.,: Is Image-Guided Surgery Right For Your Facility?. Outpatient Surgery Magazine. July 2003

#### SPEAKING ENGAGEMENTS & INSTRUCTIONAL COURSES

1. Sinus Masters Course; Chicago, Illinois; Image-Guided Surgical Instructor; December 2001
2. Mount Sinai Medical Center, Department of Otolaryngology - Grand Rounds; New York, New York; Evaluating Image Guided Surgical Systems; Lecturer; November 2002
3. Annual Combined Meeting; Oklahoma & Arkansas State Otolaryngology Societies;

- Branson, Missouri; Image-Guided Surgery Lecturer & Panel Participant; May 2002
4. Sinus Masters Course; Dallas, Texas; Image-Guided Surgical Instructor; June 2002
  5. American Academy Ambulatory Surgical Centers – Annual Meeting; New Orleans, Louisiana; Image-Guided Surgery: Using Technology To Grow Your ASC; Lecturer; March 2003
  6. Ambulatory Surgical Center and Specialty Surgical Hospital Development Conference; Getting Started: Clinical & Business Perspectives on Developing and Operating Ambulatory Surgical Centers and Surgical Hospitals; Las Vegas, Nevada; New Technology & Image Guidance Lecture; April 2003
  7. American Academy Otolaryngology Head & Neck Surgery – Annual Meeting; Orlando, Florida; Instructional Course – Image Guided Surgical Systems: Evaluation & Business Plan Development; Instructor; September 2003
  8. Buffalo Otolaryngology Society – Quarterly Meeting; Buffalo, New York; Indications and Business Plan Development For The Purchase of an Image Guided Surgical System; October 2003

**Exhibit B**  
**Sinus surgery set up devices**

- Scope & Irrigator
  - light cord
  - camera & cord
  - suction tubing
  - irrigation tubing
- Debrider
  - power cord
  - suction tubing
- Headlight
  - light cord
- Cautery
  - power cord
- Suction Tubing
- On The Floor
  - cautery peddle
  - debrider control